

## **REMARKS**

The present application is directed to an apparatus and method for processing a fluid sample. Claims 1-17 and 25-48 are currently pending. Claims 18-24 were withdrawn without prejudice as directed to a non-elected invention and canceled in a previous paper, and Claim 6 is canceled in this paper. Claims 1, 7, 8, 25, 36 and 40 have been amended, and new claim 48 has been added. Support for the amendments and new claim is set forth below. No new matter has been added. Favorable consideration of the currently pending claims is respectfully requested in light of the foregoing amendments and following remarks.

### ***Support for Claim Amendments and New Claim***

Claims 1 and 25 have been amended to incorporate the subject matter of Claim 6, which has been canceled. The dependency of Claims 7 and 8 has been amended to reflect cancellation of Claim 6.

Claims 36 and 40 have been amended to recite that they relate to “single use” rather than disposable platforms. In order to reinforce and characterize the concept that the platforms are essentially for disposal after one use, it has been previously explained that the chambers are integrated with the platform. This is disclosed on page 20 of the specification, which provides that in some embodiments the chambers may be exchangeable, which implicitly recites that in other embodiments they may not. In addition, the presence of one or more functional components has been added to Claims 36 and 40 as described on page 4 (last 2 lines), which describes the functional component in accordance with the amendment to Claim 40, and page 11 (lines 18-19), which refers to “one or more” functional components.

Support for new Claim 48 can be found in the original specification at page 21 (2<sup>nd</sup> paragraph), page 31 (last 3 lines) and original Claim 6.

***Rejections Under 35 U.S.C. § 102***

Claims 1, 3-5, 15 17, 25, 30, 31 and 35 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hiramatsu *et al.* (EP 1219965, “Hiramatsu”). Applicants respectfully traverse in view of the above amendments and following remarks.

Independent Claims 1 and 25 have been amended as described above to incorporate the subject matter of Claim 6, which was not subject to this novelty rejection. Moreover, Hiramatsu does not describe the use of solid agents able to bind analytes. Nor, in view of the specific types of manipulations contemplated by Hiramatsu, would it be obvious to utilize such agents in the procedures of Hiramatsu. Accordingly, applicants submit that Claims 1 and 25 are novel in view of Hiramatsu.

Claims 3-5, 15, 17, 30, 31 and 35 are dependent on Claim 1 or 25 and incorporate all of their limitations. Applicants thus submit that these claims are allowable as dependent on allowable independent claims and request that their rejections be withdrawn.

***Rejections Under 35 U.S.C. § 102/103***

Claims 1-6, 8, 9 and 11-13 are rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious in view of, Koike *et al.* (US 5,305,650, “Koike”). Applicants respectfully traverse in view of the above amendments and following remarks.

Koike describes an automatic preparation apparatus having a rotatable platform 15 containing various containers, a probe needle 26 and an arm 33 which can move the probe needle 26 relative to the containers.

Applicants have previously amended the claims to recite that the functional component is releasably stored on the platform and Applicants have argued that this distinguishes the device from that of Koike. Koike could not store the probe needle 26a on the platform because it is attached to a micro-syringe pump 28a through an “extendible flexible pipe” (see col. 5 lines 46-49). If the needles were stored on the platform while it is moved, there is a substantial risk that this pipe would be entangled or damaged. Applicants submit that the Office Action (“Action,” see paragraph bridging pages 26-27) improperly

rejects this argument. Specifically, the Action suggests that the probe needles are stored on the rack means and that they may therefore be exchanged between the platform and the rack. This is, in fact, incorrect—the section of Koike referred to in the Action (Koike, col. 14 lines 26-44) makes it abundantly clear that it is “small capacity containers, such as filtrate containers, transfer containers and diluted liquid containers” that may be stored on the rack means and transferred to the platform by means of an appropriate robot. There is absolutely no suggestion that the probe needles may be stored on this rack. Examination of the specific embodiment in Figure 1 and Figure 2 shows rack means 11, which is, in accordance with the description at col. 5 lines 19-21, “provided in a stationary state in a position different to the turntable and is so arranged to accommodate many **sample containers**.” The probe needles 26, which could be considered to be equivalent to the functional components of the present claims, are stored separately and remotely from the rack means.

The robot means 13 is arranged to transfer containers “between the container storage region 18 on the turntable 15 and the container storage region on the rack means 11” (col. 5, lines 55-57), but does **not** do the same with the probe needles 26. These are used as necessary in the procedure and then returned to their own storage area which contains a cleaning mechanism for them 68 (see col. 8 lines 59-65).

Accordingly, applicants submit that it cannot be obvious to store the probe needles on the platform of the Koike device as alleged in the Action since Koike provides no suggestion or motivation to do so. Furthermore, as has been previously explained, the pipes connected to the probe needles would make their storage on the moveable platform unworkable. Accordingly, Applicants submit that Claim 1 is not anticipated by, and is not obvious in view of, Koike.

Claims 2-5, 8, 9, and 11-13 are dependent on Claim 1 and incorporate all of its limitations. Applicants thus submit that these claims are allowable as dependent on an allowable independent claim and request that their rejections be withdrawn.

Claims 1, 5-7, 8, 10, 15-17, 25-27, 30-38 and 40-47 are rejected under 35 U.S.C. § 103(a) as obvious in view of Koike and Jang (USPGPUB 2003/0082565, “Jang”). Applicants respectfully traverse in view of the above amendments and following remarks.

Independent Claims 1 and 25 have been amended as described above to incorporate the limitations of Claim 6, which is not subject to the present rejection. For at least this reason, applicants submit that amended Claims 1 and 25 are not obvious in view of the Koike/Jang combination.

In addition, Koike does not teach apparatus or platforms that are adapted to **store** probe needles for the reasons set forth above. Jang does not cure the deficiencies of Koike with regard to the storage of any functional components. In fact, Jang teaches away from this arrangement since it suggests (in para. [0017]) that the container with the reagents and the cover that includes the “functional component” should be packaged **separately**.

With respect to platform Claims 36 and 40, applicants submit that the amendments to these claims clearly distinguish the present platforms from those described in Koike in that they are directed to single use or disposable platforms in which the chambers containing the predisposed reagents for a nucleic acid amplification are **integrated with** the platform. In other words, they would be disposable together and be for single use apparatus. Koike clearly does not describe such an apparatus, since both the platform and the probe needles are fully integrated into the apparatus, with the latter being washed between uses.

Moreover, there is nothing that would motivate a skilled person reading Koike to consider trying to utilize a disposable platform such as the proposed by Jang since this is clearly contrary to the basic principles of Koike, which are that samples are placed in containers for treatment within a reusable apparatus. Even if they did, however, there would be no reason to consider adding a further releasable functional component to such a platform, according to Claims 36 and 40 as currently amended.

The inventions described in Claims 36 and 40 relate to a disposable platform for single use including the reagents necessary for processing a sample and where complex operations may be carried out using a plurality of functional components, which are themselves also disposable. These inventions are certainly not taught or suggested by Koike,

which is not directed to disposable ‘single use’ devices. Moreover, the simple arrangement of Jang cannot carry out complex operations since it includes just a single “functional component” that is only able to facilitate the transfer of magnetic beads from one chamber to another.

For at least the reasons discussed above, applicants submit that independent claims 1, 25, 36 and 40 are not obvious in view of Koike and Jang, and applicants respectfully request that the rejections of these claims under 35 U.S.C. § 103(a) be withdrawn.

Claims 5, 7, 8, 10, 15-17, 26, 27, 30-35, 37, 38 and 41-47 are dependent on Claims 1, 25, 36 or 40 and incorporate all of their limitations. Applicants thus submit that these claims are allowable as dependent on an allowable independent claim and request that their rejections be withdrawn.

Claims 1 and 14 are rejected under 35 U.S.C. § 103(a) as obvious in view of Koike and Lee (WO 98/24548). Lee does not cure the deficiencies of Koike discussed above, and independent Claim 1 (and dependent Claim 14 which incorporates all of the limitations thereof) are thus allowable for the reasons discussed above.

Claims 25, 27-29, 36, 38 and 39 are rejected under 35 U.S.C. § 103(a) as obvious in view of Koike, Jang and Heath *et al.* (USPGPUB 2004/0092731, “Heath”). Heath does not cure the deficiencies of Koike and Jang discussed above, and independent Claims 25 and 36 (and dependent Claims 27-29, 38 and 39 which incorporate all of the limitations of Claim 25 or 36) are thus allowable for the reasons discussed above.

Claims 36-38 and 40-47 are rejected under 35 U.S.C. § 103(a) as obvious in view of Squirrell (WO 2002/087762) and Jang. Applicants respectfully traverse in view of the above amendments and following remarks.

Claims 36 and 40 have been amended as provided above to recite the presence of a further structural component that is releasably held on the platform and which is also utilized in the context of the processing. This represents a further distinction from the disclosure of

Squirrell, which includes just a single functional component in the form of a plunger, which acts to move liquids by overflowing them from the chambers, as well as acting as a sheath for a magnet. There would be nothing to motivate a skilled person to add further functional components to the apparatus of Squirrell since there is apparently no need for such components in the apparatus and processes described. Moreover, for the reasons discussed above Jang does not disclose or suggest the subject matter of amended Claims 36 and 40. Accordingly, independent Claims 36 and 40 (and dependent Claims 37, 38 and 41-47 which incorporate all of the limitations of Claim 36 or 40) are thus allowable for the reasons discussed above.

Claims 36, 38 and 39 are rejected under 35 U.S.C. § 103(a) as obvious in view of Squirrell, Jang and Heath. Heath does not cure the deficiencies of Squirrell and Jang discussed above, and independent Claim 36, and dependent Claims 38 and 39 which incorporate all of the limitations of Claim 36, are thus allowable for the reasons discussed above.

Claims 1, 5-11, 15-16, 25, 32, 40-44, 46 and 47 are rejected under 35 U.S.C. § 103(a) as obvious in view of Hiramatsu and Jang. Amended independent Claims 1, 25 and 40, and the deficiencies of Hiramatsu and Jang related thereto, are discussed above. Specifically, neither of these references disclose or suggest the inclusion of more than one functional component on the platform. Accordingly, for at least the reasons discussed above applicants submit that independent Claims 1, 25 and 40 are not obvious in view of Hiramatsu and Jang, and applicants respectfully request that the rejection of these claims be withdrawn.

Claims 5, 7-11, 15-16, 32, 41-44, 46 and 47 are dependent on Claims 1, 25 or 40 and incorporate all of their limitations. Applicants thus submit that these claims are allowable as dependent on an allowable independent claim and request that their rejections be withdrawn.

Claims 1 and 14 are rejected under 35 U.S.C. § 103(a) as obvious in view of Hiramatsu and Lee. Lee does not cure the deficiencies of Hiramatsu discussed above, and

independent Claim 1 and dependent Claim 14 which incorporates all of the limitations thereof are thus allowable for the reasons discussed above.

***New Claim***

New Claim 48 includes the recitation that the apparatus comprises “at least three sealed chambers comprising predispensed reagents for use in processing of a fluid sample prior to a nucleic acid amplification reaction arranged on the platform, wherein at least one of the chambers comprises a solid phase binding material capable of forming a complex with the analyte, at least one of the chambers comprises a wash solution, and at least one of the chambers comprises water into which nucleic acid can be eluted.”

None of the cited references disclose or suggest such an arrangement. Accordingly, applicants request that Claim 48 be given favorable consideration.

**CONCLUSION**

The foregoing is submitted as a full and complete response to the Office Action mailed February 25, 2010.

Applicants assert that the claims are in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case that may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

No additional fees are believed due; however the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account Number 11-0855.

Respectfully submitted,

/Christopher M. Durkee/

By: Christopher M. Durkee  
Reg. No. 59,640

KILPATRICK STOCKTON LLP  
1100 Peachtree Street, Suite 2800  
Atlanta, Georgia 30309-4530  
Telephone: (404) 815-6500  
Facsimile: (404) 815-6555  
Our Docket: 41577-326422 (P1348US00)